MAY 1 6 2001

K003609

Appendix A

Summery of Safety and Effectiveness:

Name of Device:	N-MID™ Osteocalcin One Step ELISA K003609
Classification Name:	Enzyme immunoassay, Osteocalcin Alkaline Phosphatase or isoenzymes test system
Analyte Code and Name:	CIN
Submitter:	Osteometer BioTech A/S Herlev Hovedgade 207 DK-2730 Herlev
Date:	February 22, 2001

N-MID™ Osteocalcin One Step ELISA kit was developed for the quantitative measurement of osteocalcin in human plasma and serum.
The EIA format is sandwich assay.
The assay is based upon the application of two highly specific monoclonal antibodies (Mab) against human osteocalcin. An antibody recognizing the middle region (amino acids 20-43) is used as the capture antibody and for detection a peroxidase conjugated antibody recognizing the N-terminal region (amino acids 1-19) is used. In addition to intact osteocalcin (amino acid 1-49) the N-terminal-Mid fragment (amino acids 1-43) is also detected.
First, standards (synthetic osteocalcin), control or unknown samples are pipetted into the appropriate wells of microtitre strips coated with streptavidin (immuno strips). Then a mixture of a biotinylated antibody and a peroxidase conjugated antibody (HRP-conjugated Mab) is added. Following incubation for 2 hours at room temperature the wells are washed and a chromogenic substrate (TMB) is added. The reaction is stopped after 15 minutes and the absorbency is measured.

This pre-market notification demonstrates that the N-MID™ Osteocalcin One Step ELISA for the quantitative measurement of osteoblastic activity in plasma and serum is substantially equivalent to Tandem®-R Ostase™ immunoradiometic Assay that was cleared by FDA in a previous submission (#K961573)

This pre-market notification also includes clinical data demonstrating that:
The N-MID ™Osteocalcin One Step ELISA assay is intended for in vitro diagnostic use for the quantitative measurement of osteocalcin in serum and plasma as an indication of human bone formation and osteoblastic activity and may be used as an aid in the prevention of postmenopausal osteoporosis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 16 2001

Ms. Eva Gamwell Henriksen
Head of Regulatory Affairs
Osteometer Biotech A/S
Osteopark
Herlev Hovedgade 207
DK-2730 Herlev
Denmark

Re: 510(k) Number: K003609
Trade/Device Name: N-MID™ Osteocalcin One Step ELISA
Regulation Number: 862.1050
Regulatory Class: II
Product Code: NEO
Dated: March 1, 2001
Received: March 5, 2001

Dear Ms. Henriksen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K003609

Device Name: N-MID™ Osteocalcin One Step ELISA

Indications for use:

The N-MID™ Osteocalcin One Step ELISA assay is intended for in vitro diagnostic use for the quantitative measurement of osteocalcin in serum and plasma as an indication of human bone formation and osteoblastic activity and may be used as an aid in the prevention of postmenopausal osteoporosis.

(Division Sign-Off)
Division of Clinical Labora...
510(k) Number K003609

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ **OR** **Over-The-Counter Use**_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)